DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-061/S-011
NDA 21-061/S-015
NDA 21-062/S-015

Bristol-Myers Squibb Company
Attention: Joan C. Fung-Tomc, Ph.D.
5 Research Parkway
Wallingford, CT 06492-7660

Dear Dr. Fung-Tomc:

Please refer to your supplemental new drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product	NDA Number	Supplement Number	Date of Supplement	Date of Receipt
Tequin (gatifloxacin) Tablets, 200 and 400 mg	21-061	S-011	August 1, 2001	August 2, 2001
		S-015	October 11, 2001	October 12, 2001
Tequin (gatifloxacin) for Injection, 200 and 400 mg	21-062	S-015	October 11, 2001	October 12, 2001

We acknowledge receipt of your submissions dated as follows:

NDA 21-061/S-011	October 18, 2001
	January 10, 2002
	March 5, 2002
	March 25, 2002
	April 24, 2002
	May 13, 2002
	October 21, 2002
	November 14, 2002
	November 22, 2002
NDA 21-061/S-015	May 13, 2002
	September 30, 2002
	October 21, 2002
	November 14, 2002
	November 22, 2002
NDA 21-062/S-015	May 13, 2002
	September 30, 2002
	October 21, 2002
	November 14, 2002
	November 22, 2002

Your submission of September 30, 2002 (NDA 21-061/S-011) constituted a complete response to our action letter of September 18, 2001.

NDA 21-061/S-011 provides for a new trade pack (carton) of three 5-tablet blister cards of Tequin Tablets, 400 mg (i.e., 15 tablets/carton).

NDA 21-061/S-015 and 21-062/S-015 provide for revision of the package insert under **HOW SUPPLIED** to add information regarding a 5-tablet blister card and a carton of three 5-tablet blister cards for Tequin Tablets, 400 mg. These supplements also provide for revision of carton and blister card artwork to reflect a change from a 7-tablet blister card to a 5-tablet blister card and from a carton of two 7-tablet blister cards to a carton of three 5-tablet blister cards.

These three supplements provide for the following revisions to the Tequin® label and to the Tequin® Teq-Paq blister card and carton. The deleted text is noted by ~~strikethrough~~ and the added text is noted by single underline as follows:

1. Package insert: **HOW SUPPLIED**

Tablets
TEQUIN® (gatifloxacin) Tablets are available as 200-mg and 400-mg white, film-coated tablets. The tablets are almond shaped and biconvex and contain gatifloxacin sesquihydrate equivalent to either 200 mg or 400 mg gatifloxacin.
Tequin Tablets are packaged in bottles, unit dose blister strips, and multidose blister packs of ~~7~~ 5 tablets (Tequin Teq-Paq™) in the following configurations:

200 mg tablets – color: white; shape: biconvex; debossing: "BMS" on one side and "TEQUIN" and "200" on the other.
Bottles of 30 (NDC 0015-1117-50)
Blister pack of 100 (NDC 0015-1117-80)
400 mg tablets – color: white; shape: biconvex; debossing: "BMS" on one side and "TEQUIN" and "400" on the other.
Bottles of 50 (NDC 0015-1177-60)
Blister pack of 100 (NDC 0015-1177-80)
~~Carton of 2 TEQUIN Teq-Paqs (7 tablets each)(NDC 0015-1177-19)~~
Carton of 3 TEQUIN Teq-Paqs™ (5 tablets each) (NDC 0015-1177-21)

2. Carton and blister card

   a. The 5-tablet carton has blue words with red artwork on a white background. The 5-tablet blister card has blue and red words with red artwork on a white background. The 7-tablet carton and blister card had blue and red words and blue artwork on a white background.

   b. The statement "See package insert for complete dosage information" on the back panel on the 7-tablet Teq-Paq™ carton has been changed on the 5-tablet Teq-Paq™ carton to "Usual Dosage: Take 1 tablet orally once a day. See package insert."

   c. The words "REMEMBER TO TAKE YOUR TEQUIN®" that were on the front and both side panels of the 7-tablet Teq-Paq™ carton have do not appear on the 5-tablet Tequin Teq-Paq™ carton. The words "REMEMBER TO TAKE YOUR TEQUIN®" that

were on the front panel of the 7-tablet blister card under the words "TEQUIN Teq-Paq" have been replaced with "Each Teq-Paq contains 5 tablets" on the 5-tablet blister card. In addition, the NDC number has been changed from 0015-1177-19 on the front panel of the 7-tablet blister card to 0015-1177-21 on the front panel of the 5-tablet blister card.

d. The words "2 TEQUIN Teq-Paqs™ enclosed. Each TEQUIN Teq-Paq™ contains 7 tablets." have been changed to "3 TEQUIN Teq-Paqs™ enclosed. Each TEQUIN Teq-Paq™ contains 5 tablets." on the top and bottom panels of the carton.

e. On the blister card, one of the panels has been revised from:

~~**TEQUIN® (gatifloxacin), an antibiotic that you take once daily, has been prescribed to treat your infection.**~~

~~• Take 1 tablet orally each day until your medication is gone.~~

~~• You can take TEQUIN with or without food.~~

~~**The TEQUIN Teq-Paq® will help make Tequin easy to remember and convenient to carry.**~~

~~• Try to take TEQUIN about the same time each day.~~

~~• Be sure to take all medication you've been given even if you feel better.~~

~~See package insert for complete dosage information.~~

to:

• Take 1 tablet orally each day until all tablets are gone.

• You can take TEQUIN about the same time each day.

• Try to take TEQUIN about the same time each day.

• Make sure you take Tequin for 5 days even if you feel better.

See package insert for complete dosage information.

f. On one panel of the blister card, the statement "See package insert for complete dosage information." has been changed to "Usual Dosage: Take 1 tablet orally once a day. See package insert."

g. The two panels on the blister card that contained openings for 7 tablets now contain openings for 5 tablets.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are

safe and effective for use as recommended in the agreed upon labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) and submitted draft labeling (blister card submitted September 30, 2002; carton submitted November 22, 2002).

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL, blister card, and carton to each supplement as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplements NDA 21-061/S-011, NDA 21-061/S-015, and NDA 21-062/S-015." Approval of these submissions by FDA is not required before the labeling is used.

If you issue a letter communicating important information about these drug products (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to NDAs 21-061 and 21-062 and a copy to the following address:

MEDWATCH, HF-2
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Diana Willard, Regulatory Project Manager, at (301) 827-2127.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, M.D.
Director
Division of Special Pathogen and Immunologic Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Renata Albrecht

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